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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/047,204	01/14/2002	Alan J. Dextradeur	022719-0027	5062
21125 7590 11/19/2004			EXAMINER	
NUTTER MCCLENNEN & FISH LLP			DEAK, LESLIE R	
WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 11/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
	10/047,204	DEXTRADEUR ET AL.				
Office Action Summary	Examiner	Art Unit				
	Leslie R. Deak	3762				
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with	the correspondence address				
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a rep by within the statutory minimum of thirty (will apply and will expire SIX (6) MONTH be, cause the application to become ABA	ly be timely filed (30) days will be considered timely. HS from the mailing date of this communication. NDONED (35 U.S.C. § 133).				
Status		1				
1) Responsive to communication(s) filed on 25 A	ugust 2004.					
2a)⊠ This action is FINAL . 2b)☐ This	This action is FINAL . 2b) ☐ This action is non-final.					
,—	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
closed in accordance with the practice under a	_x parte Quayle, 1935 O.D.	11, 400 0.0. 210.				
Disposition of Claims						
Claim(s) <u>1-27</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.	Claim(s) is/are allowed.					
6)⊠ Claim(s) <u>1-27</u> is/are rejected.	☑ Claim(s) <u>1-27</u> is/are rejected.					
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	or election requirement.					
Application Papers						
9)☐ The specification is objected to by the Examine	er. 、					
10)⊠ The drawing(s) filed on 14 January 2002 is/are)⊠ The drawing(s) filed on <u>14 January 2002</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.					
Applicant may not request that any objection to the	drawing(s) be held in abeyance	e. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correct						
11)☐ The oath or declaration is objected to by the E	xaminer. Note the attached (Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for foreign	priority under 35 U.S.C. § 1	I19(a)-(d) or (f).				
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority document	ts have been received in Ap	plication No				
3. Copies of the certified copies of the prior	rity documents have been re	eceived in this National Stage				
application from the International Burea						
* See the attached detailed Office action for a list	of the certified copies not re	eceived.				
Attachment(s) 1) \(\sum \) Notice of References Cited (PTO-892)	4) Interview Su	mmary (PTO-413)				
2) Notice of References Cited (PTO-092) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/	Mail Date				
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	5) Notice of Info 6) Other:	ormal Patent Application (PTO-152) 				

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DETAILED ACTION

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Claim Rejections - 35 USC § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 2. Claims 1-8, 12-17, and 19-22 are rejected as being unpatentable over US 4,925,452 to Melinyshyn et al. in view of US 4,432,853 to Banks. Melinyshyn discloses a drainage catheter with a drainage conduit 36 and a manifold 34 that holds multiple drainage conduits, A and B, each with their own lumen. The manifold connects the secondary catheters to the main catheter, and the secondary catheters are supported by a membrane that supports the multiple conduits and may space them apart from one another to form a center space between the two conduits (see column 2, FIGS 2-4).
- 3. Melinyshyn fails to disclose that the primary and secondary catheters are formed in an integral unit and that the support is formed of a bioabsorbable material. It would have been obvious to one of ordinary skill in the art at the time of invention to form the device in an integral unit, since it has been held that forming in once piece an article that has formerly been formed in two pieces and put together involves only routine skill in the art. See MPEP 2144.04. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the support out f a bioabsorbable material since it has been held to be within the general skill of a worked

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in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. See MPEP 2144.07.

- 4. Melinyshyn discloses the device as claimed with the exception of the diameter of the catheter and secondary catheters and the arrangement of the secondary catheters. Banks discloses and illustrates a drainage catheter with the option of a valve with multiple perforated microtubules within. The diameter of the microtubules is approximately the same as the main catheter and the microtubules may be sealed at the distal end (see FIG 1, column 3). Banks further discloses that the configuration of the microtubules may be adjusted, and suggests a twisted position (see column 4, lines 55-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to adjust the diameter of the secondary tubes, add drainage holes on the side of the tubes, add a valve, and twist the tubes in order to improve drainage flow and prevent clogging of the drainage catheters, as taught by Banks.
- 5. Claims 9-11,18, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,925,452 to Melinyshyn et al. in view of US 4,432,853 to Banks in view of US 4,406,656 to Hattler et al. Melinyshyn and Banks disclose the valved catheter as claimed with the exception of the location of the valve and a stylet. Rearrangement of the parts of a device disclosed in the prior art is within one of ordinary skill in the art. See MPEP 2144.04. Hattler discloses a flow catheter with a center lumen 800 that allows a guidewire or stylet to be inserted therethrough to guide the catheter into position (see FIGS 8, 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to add a guidewire or stylet to the

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multilumen catheter disclosed by Melinyshyn and Banks in order to guide the catheter into position, as taught by Hattler.

Response to Arguments

- 6. Applicant's arguments with respect to claims 1-22 have been considered but are most in view of the new ground(s) of rejection.
- 7. In response to applicant's argument that it would not have been obvious to modify the Melinyshyn device since it is designed for surgical use, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).
- 8. With regard to applicant's argument that there's no motivation to modify the Banks device, that is not the reference being modified. Banks is used as a secondary reference to modify the Melinyshyn device to solve the blockage problems inherent in the Melinyshyn device.
- 9. With regard to applicant's argument that the Hattler device does not contemplate a removable stylet, FIG 11 and the description thereof specifically address the use of a guidewire as a stylet to guide the placement of the catheter in the desired location.

 Therefore, the catheter is configured to receive a removable stylet, as claimed by applicant.

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Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16 November 2004

ANGELA D. SYKES SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 3700

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